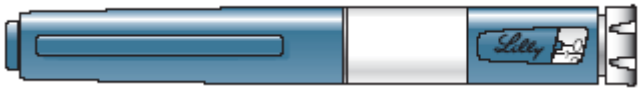
USER MANUAL

KwikPen™
Insulin delivery device



Lilly

PLEASE READ THESE INSTRUCTIONS BEFORE USE

Introduction

The **KwikPen™** is designed for ease of use. It is a disposable pen containing 3 mL (300 units) of U-100 insulin. You can inject from 1 to 60 units of insulin in one injection. You can dial your dose one unit at a time. If you dial too many units, you can correct the dose without wasting any insulin.

Before using KwikPen, read the entire manual completely and follow the directions carefully. If you do not follow these directions completely, you may get too much or too little insulin.

Your KwikPen must be used only for your injections. Do not share your pen or needles as this may risk transmission of infectious agents. Use a new needle for each injection.

DO NOT USE your pen if any part appears broken or damaged. Always carry an extra pen in case yours is lost or damaged.

This pen is not recommended for use by the blind or visually impaired persons without the assistance of a person trained in the proper use of the product.

Preparing KwikPen

Important Notes

- Read and follow the directions provided in the insulin package leaflet.
- Check the label on your pen before each injection for the expiration date and to make sure you are using the correct type of insulin. Do not remove the pen label.

  Note: The colour of your KwikPen Dose Knob matches the insulin-specific colour band shown on the Pen Label. In this user manual, the Dose Knob is shown in grey. The Pen Body is blue to indicate that it contains a Humalog family of products.

Dose Knob Colour-code key:

Humalog	Humalog Mix25	Humalog Mix50

- Your healthcare professional has prescribed the most appropriate type of insulin for you. **Any changes in insulin therapy should be made only under medical supervision.**

- **KwikPen** is recommended for use with Becton, Dickinson and Company (BD) pen needles.
- Be sure the needle is completely attached to the pen before use.
- Keep these directions for future reference.

Frequently Asked Questions about Preparing KwikPen

- **What should my insulin look like?** Some insulins are cloudy while others are clear, be sure to refer to your insulin package leaflet for the appearance of your specific insulin.

- **What do I do if my dose is higher than 60 units?** If your dose is higher than 60 units of insulin, multiple injections will be required or you may contact your healthcare professional.

- **Why should I use a new needle for each injection?** If needles are reused, you may get the wrong amount of insulin, a clogged needle, a jammed pen, or an infection, because sterility is not ensured.

- **What should I do if I am not sure how much insulin remains in my cartridge?** Hold the pen with the needle end pointing down. The scale on the clear Cartridge Holder shows an estimate of the number of units remaining. **These numbers should NOT be used for measuring an insulin dose.**

- **What should I do, if I can't remove the Pen Cap?** Pull the cap straight off. If you are having difficulty removing the cap, gently twist the cap back and forth to realign, and then pull the cap straight off.

Priming KwikPen

Important Notes

- **Prime every time**. The pen must be primed to a stream of insulin before each injection to make sure the pen is ready to dose.
- **If you do not prime to a stream, you may get too much or too little insulin.**

Frequently Asked Questions about Priming

- **Why should I prime my pen before each dose?**
    1. Ensures that the pen is ready to dose.
    2. Confirms that a stream of insulin comes out of the tip of the needle when you push the Dose Knob in.
    3. Removes air that may collect in the needle or insulin cartridge during normal use.

- **What should I do if I cannot completely push in the Dose Knob when priming KwikPen?**
    1. Attach a new needle.
    2. Prime the pen.

- **What should I do if I see an air bubble in the cartridge?** You need to prime the pen. Remember, do not store the pen with the needle attached as this may cause air bubbles to collect in the insulin cartridge. A small air bubble will not affect your dose and you can continue to take your dose as usual.

Injecting Your Dose

Important Notes

- Follow the instructions for sanitary injection technique recommended by your healthcare professional.
- Make sure you receive your complete dose by pushing and holding the dose knob in and **count to 5 slowly** before removing the needle. If insulin is leaking from the pen you may not have held it in your skin long enough.
- A drop of insulin at the needle tip is normal. It will not affect your dose.
- The pen will not allow you to dial more than the number of units left in the pen.
- **If you do not think you received your full dose, do not take another dose.** Call Lilly or your healthcare professional for assistance.
- If your dose is greater than the number of units left in the pen, you may either inject the amount remaining in your current pen and then use a new pen to complete your dose, OR inject the full dose with a new pen.
- Do not attempt to inject your insulin by *turning* the Dose Knob. You will NOT receive your insulin by turning the Dose Knob. **You must PUSH the Dose Knob straight in for the dose to be delivered.**
- Do not attempt to change the dose while injecting.
- The directions regarding needle handling are not intended to replace local, healthcare professional and/or institutional policies.
- Remove the needle after completing each injection.

Frequently Asked Questions about Injecting Your Dose

- **Why is it difficult to push the Dose Knob when I try to inject?**
    1. Your needle may be clogged. Try attaching a new needle. When you do this you may see insulin come out of the needle. Then prime the pen.
    2. Pressing the Dose Knob quickly may make the Dose Knob harder to push. Pressing the Dose Knob more slowly may make it easier.
    3. Using a larger diameter needle will make it easier to push the Dose Knob during your injection. See your healthcare professional to determine which needle size is best for you.
    4. If the Dose Knob continues to be difficult to push after following the steps above, you may need a new pen.

- **What should I do if my KwikPen is jammed?** Your pen is jammed if it is difficult to inject a dose or dial a dose. To clear the jam:
    1. Attach a new needle. When you do this you may see insulin come out of the needle.
    2. Prime the pen.
    3. Dial your dose and inject.

  Do not attempt to lubricate your pen as this may damage the mechanism.

  The Dose Knob may become harder to push, if foreign material (dirt, dust, food, insulin, or other liquids) get inside the pen. Avoid getting foreign material inside the pen.

- **Why is insulin leaking from the needle after I finished my dose?** You may have removed the needle from your skin too quickly.
    1. Make sure you see a 0 in the Dose Window.
    2. For the next dose, **push and hold** the Dose Knob in and **count to 5 slowly** before removing the needle.

- **What should I do if my dose is dialled and the Dose Knob is accidentally pushed in without a needle attached?**
    1. Dial back to zero.

2. Attach a new needle.
3. Prime the pen.
4. Dial your dose and inject.

- **What should I do if I dial a wrong dose (too high or too low)?** Turn the Dose Knob backward or forward to correct the dose.

- **What should I do if I see insulin leaking from the pen needle while dialling the dose or correcting the dose?** Do not inject the dose because you may not get your complete dose. Dial the pen down to zero and prime the pen again (see **Routine Use** section "Priming KwikPen" steps 2B thru 2D). Dial your dose and inject.

- **What should I do if my full dose cannot be dialled?** The pen will not allow you to dial a dose greater than the number of insulin units remaining in the cartridge. For example, if you need 31 units and only 25 units remain in the cartridge you will not be able to dial past 25. Do not attempt to dial past this point. If a partial dose remains in the pen you may either:
    1. Give the partial dose and then give the remaining dose using a new pen.

    or

    2. Give the full dose with a new pen.

- **Why can I not dial the dose to use the small amount of insulin that remains in my cartridge?** The pen is designed to deliver at least 300 units of insulin. The pen design prevents the cartridge from being completely emptied because the small amount of insulin that remains cannot be delivered accurately.

Storage and Disposal

Important Notes

- Before the first use store your pen in a refrigerator (2°C – 8°C). Do not use a pen if it has been frozen.
- Keep your pen in use at room temperature and away from heat and light.
- Do not store the pen with the needle attached. If the needle is left on, insulin may leak from the pen, insulin may dry inside the needle causing the needle to clog, or air bubbles may form in the cartridge.
- Refer to the package leaflet for complete insulin storage instructions.
- After first use the pen should not be used beyond the time specified in the insulin package leaflet.
- Dispose of used needles in a closable, puncture-resistant container or as directed by your healthcare professional.
- Dispose of used pens as instructed by your healthcare professional and without the needle attached.
- Do not recycle the filled sharps container.
- Ask your healthcare professional about options available in your area to throw away the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional, or institutional policies.
- Keep the pen out of the reach of children.

If you have any questions or problems with your KwikPen, **contact your healthcare professional for assistance.**

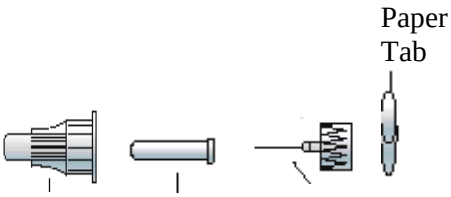
Getting Ready

Make sure you have the following items:

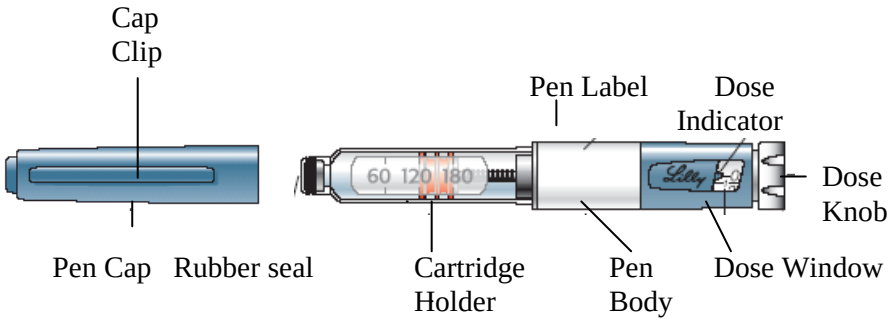
- ❑ **KwikPen**
- ❑ **New Pen Needle**
- ❑ **Alcohol Swab**

Pen Parts KwikPen and Needle* Assembly ***sold separately**

Pen Needle Parts (Needles Not Included)



KwikPen Parts



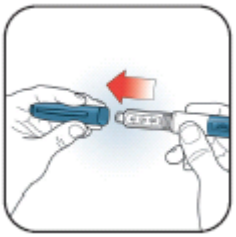
Dose Knob Colour-code key:

Humalog	Humalog Mix25	Humalog Mix50

Routine Use Follow these instructions for each injection

1. Preparing KwikPen

A.



Pull Pen Cap straight off to remove. Do not twist the cap. **Do not remove the Pen Label.**

Be sure to check your insulin for:

- Type
- Expiration date
- Appearance

Caution: Always read the Pen Label to ensure you are using the correct insulin type.

B.

For Cloudy Insulin only:

Gently roll the pen 10 times.

And

Invert the pen 10 times.

Mixing is important to make sure you get the right dose. The insulin should look evenly mixed.

C.

Select a new needle.

Remove paper tab from Outer Needle Shield.

Use an alcohol swab to wipe the Rubber Seal on the end of the Cartridge Holder.

D.

Push capped needle **straight** onto the pen.

Screw needle on until secure.

2. Priming KwikPen

Caution: If you do not prime to a stream before each injection, you may get too much or too little insulin.

A.

Pull off Outer Needle Shield. **Do not** throw away.

Pull off Inner Needle Shield and throw away.

B.

Dial 2 Units by turning the Dose Knob.

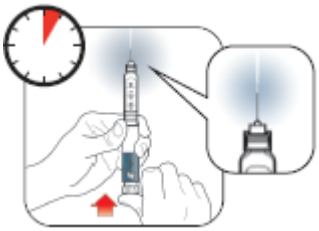
C.

Point pen up.

Tap Cartridge Holder to collect air at top.

D.

- With needle pointed up, push Dose Knob in until it stops and 0 is seen in the Dose Window.
- Hold Dose Knob in and **count to 5 slowly.**
- Priming is complete when a stream of insulin appears from the needle tip.
- If a stream of insulin does not appear, repeat priming steps 2B thru 2D up to four times.



Note: If you do not see a stream of insulin from the needle tip and dialling the pen is more difficult, change the needle and prime the pen.

3. Injecting Your Dose

A.

Turn Dose Knob to the number of units you need to inject. If you dial too many units, you can correct the dose by dialling backwards.

B.

Insert needle into skin using injection technique recommended by your healthcare professional.

Place your thumb on the Dose Knob and push firmly until the Dose Knob stops moving.

To deliver the full dose, hold Dose Knob in and **count to 5 slowly**. Remove needle from skin.

Note: Check to make sure you see 0 in the Dose Window to confirm you received the complete dose.

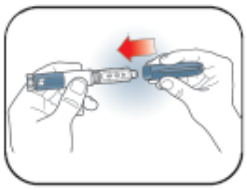
C.

Carefully replace the Outer Needle Shield.

Note: Remove the needle after each injection to keep air out of the cartridge.
Do not store the pen with the needle attached.

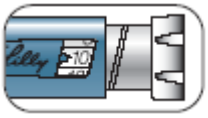
D.

Unscrew the capped needle and throw away as directed by your healthcare professional.

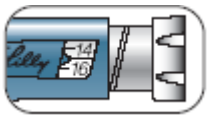


Replace Pen Cap by aligning the Cap Clip with the Dose Window and pushing straight on.

Example: 10 units shown.



Example: *15 units shown.*



The **even** numbers are printed on the dial. The **odd** numbers, after the number one, are shown as full lines.

Note: The pen will not allow you to dial more than the number of units left in the pen.

If you do not think you received your full dose, do not take another dose.

Document revision date: September 2013